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10/028,914	12/28/2001	Yoshihide Murakami	Q67950	2679

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EXAMINER

CHANG, VICTOR S

ART UNIT	PAPER NUMBER
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/028,914
Filing Date: December 28, 2001
Appellant(s): MURAKAMI ET AL.

MAILED

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GROUP 1700

Peter Olexy
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 20, 2006 appealing from the Office action mailed August 18, 2005.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: Appellants' identification of rejection of claims 17 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite, is no longer considered applicable by the Examiner and hereby withdrawn.

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. More particularly, since the rejection under 35 USC 112, second paragraph in section 5 of Office action mailed

8/18/2005 was mainly directed to cancelled claims 1-9 (see after-final amendment filed 1/17/2006), it has been withdrawn, and is not presented for review on appeal, as set forth above.

NEW GROUND(S) OF REJECTION

In view of Appellants cancellation of claims 1-9, and the incorporation of the limitations in cancelled claim 1 into originally dependent claim 17, a new ground of rejection of claims 17 and 18 under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Webster (US 4541426) is included in this Examiner's Answer for review.

Claims 17 and 18 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Webster (US 4541426).

Webster's invention is directed to a conformable (flexible and having "skin follow-up property") film suitable for application to lesions of the skin (i.e., wound dressing). The film consists of two layers laminated together, the first layer which is the lesion contacting layer is formed from a material which swells in contact with water (Abstract). Suitably, the first layer, which contacts the wet surface of the lesion, will be formed from a hydrophilic polymer, such as films of blends of polyurethane with polyvinyl pyrrolidone, etc. Aptly, such a hydrophilic polymer will contain between 5 and 95% by weight water when hydrated (column 2, line 49 to column 3, line 2). An adhesive may be applied over the entire surface of the first layer so that when in use the dressing is adhered to the intact skin (column 5, lines 63-65). Finally, regarding the tensile moduli of the hydrophilic polymer and the elastomer resin, and their blend in wet and dry states, since

Webster expressly teaches a film comprising the same hydrophilic polymer (polyvinyl pyrrolidone), the same type of elastomers (polyurethanes) as shown in cancelled claims 6 and 4 of instant invention (see original claims filed 12/28/2006), and for the same use (wound dressing) as the instant invention (see specification of instant invention, page 7, third full paragraph), and the utility disclosed dictates there would be similar moduli for flexibility or conformability, it is the Examiner's position that 1) since the tensile moduli of polyvinyl pyrrolidone (hydrophilic polymer), polyether polyurethanes or polyester polyurethanes (elastomer resin) are inherent properties, in the absence of evidence to the contrary, they anticipate the claimed moduli; 2) a suitable modulus of the blend in dry and wet states are either anticipated by Webster, or obviously provided by practicing the invention of prior art. It should be noted that where the claimed and prior art products are shown to be identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. See MPEP § 2112.01.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 5,607,687	Bezwada et al.	3-1997
US 4,541,426	Webster	9-1985

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bezwada et al. (US 5607687) in view of Webster (US 4541426).

Bezwada's invention is directed to a bioabsorbable polymeric material and blends thereof and more particularly to absorbable surgical products made from such polymers and blends thereof (column 1, lines 11-14). The blends comprise polyether polyurethanes, polyester polyurethanes, polyvinyl pyrrolidone, etc., and combinations thereof (column 2, lines 17-67). Useful embodiments made of the polymer blend include sheets for areas where the skin and underlying tissues are damaged or surgically removed (i.e., a wound dressing) (column 6, lines 38-64). Bezewada lacks a teaching that a layer of an adhesive is formed on the surface of the bioabsorbable polymeric sheet. However, it is noted that Webster's invention is directed to a conformable (flexible and having "skin follow-up property") film suitable for application to lesions of the skin (i.e., a wound dressing) (abstract). The film consists of two layers laminated together, the first layer which is the lesion contacting layer is formed from a material which swells in contact with water (abstract). Suitable polymers forming the first layer, which contacts the wet surface of the lesion will be formed from a hydrophilic polymer, including blends of polyurethane with polyvinyl pyrrolidone, etc. Aptly, such a hydrophilic polymer will contain between 5 and 95% by weight water when hydrated. (column 2, line 49 to column 3, line 2). An adhesive may be applied over the entire surface of the first layer so that when in use the dressing is adhered to the intact skin (column 5, lines 63-65). As such, in the absence of unexpected results, it would have been obvious to one of ordinary skill in the art to modify Bezwada's wound dressing

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sheet with a layer of adhesive on its surface, as taught by Webster, motivated by the desire to obtain a wound dressing which can be adhered to the intact skin surrounding a wound and therefore providing more protected wound coverage. The combined teachings of Bezwada and Webster render the instant invention obvious. As to the tensile moduli of the hydrophilic polymer, the elastomer resin, and their blend in wet and dry states; since both Bezwada and Webster expressly teaches sheets of the same hydrophilic polymer (polyvinyl pyrrolidone), the same elastomers (polyether polyurethanes, polyester polyurethanes), as shown in cancelled claims 6 and 4 of instant invention (see original claims filed 12/28/2006), for the same use (wound dressing) as the instant invention (see specification of instant invention, page 7, third full paragraph), and since the utility of both Bezwada and Webster dictates that there would be similar flexibility or conformability, it is the Examiner's position that 1) the tensile moduli of polyvinyl pyrrolidone (hydrophilic polymer), polyether polyurethanes or polyester polyurethanes (elastomer resin) are inherent properties, in the absence of evidence to the contrary, they anticipate the claimed moduli; and 2) in the absence of unexpected results, a suitable modulus of the blend in dry and wet states are obvious optimization to one skilled in the art of wound dressing in order to meet the requirements of the utility set forth in the prior art. It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Finally, regarding the transition term "consisting essentially of" in claim 17, the Examiner notes that it has not been given patentable weight because Applicants have not

identified what basic and novel characteristics of claimed invention would be materially affected by the presence of polyoxaester as a main component.

(10) Response to Argument

With respect to Appellants' argument relating to a prior rejection over 35 U.S.C. 112, second paragraph (Brief, pages 8-10), the Examiner repeats that this rejection is withdrawn.

With respect to Appellants' argument "Bezwada '687 discloses bioabsorbable polymer blends containing polyoxaesters as its main component and a second polymer ... Bezwada '687 fails to teach that all polyoxaesters have a tensile modulus of elasticity higher than that of an elastomer resin ..." (Brief, pages 11-12, bridging paragraph), the Examiner reminds Appellants that 1) it is the polyvinyl pyrrolidone taught by Bezwada or Webster being relied upon as reading on the moduli of the hydrophilic polymer of the instant invention, not polyoxaester, as set forth above, Appellants' argument is clearly misplaced; and 2) while Bezwada teaches that polyoxaester is a main component, and the transition term of the instant claims is "consisting essentially of", Applicants have failed to identify what basic and novel characteristics of claimed invention would be materially affected by including polyoxaester as a main component, as such it is not seen how the phrase "consisting essentially of" is to narrow the claim scope to exclude the combined teachings of Bezwada and Webster.

With respect to Appellants' argument "... Webster '426 ... relates to a dressing useful in treating lesions of the skin ... a laminate dressing which has a reduced tendency to adhere to lesions of the skin ... Webster '426 fails to make up the

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deficiencies in Bezwada '687 ... Given that Webster '426 is relied upon for disclosing an adhesive layer ..." (Brief, pages 12-13, bridging paragraph), the Examiner notes that Appellants' argument fails to clearly point out any specific reason why Webster fails to make up the deficiencies in Bezwada, and repeats that since Webster expressly teaches that an adhesive may be applied over the entire surface of the first layer so that when in use the dressing is adhered to the intact skin, in the absence of unexpected results, it would have been obvious to one of ordinary skill in the art to modify Bezwada's wound dressing sheet with a layer of adhesive on its surface, as taught by Webster, motivated by the desire to obtain a wound dressing which can be adhered to the intact skin. Appellants' argument is not convincing.

With respect to Appellants' repeated argument "The Examiner asserts that the hydrophilic polymer recited in Claim 17 reads on polyoxaester disclosed in Bezwada '687, even though Bezwada '687 fails to expressly teach the tensile modulus ... the Examiner must provide some evidence or scientific reasoning to establish the reasonableness of the Examiner's belief that the feature is necessarily inherent in the cited art ... the Examiner has incorrectly placed this burden on Applicants ..." (Brief, pages 13-15), the Examiner again respectfully reminds Appellants that it is the polyvinyl pyrrolidone taught by Bezwada or Webster being relied upon as reading on the moduli of the hydrophilic polymer of the instant invention, not polyoxaester, as set forth above, Appellants' argument is misplaced.

With respect to Appellants' argument "... Bioabsorbability would materially alter the basic characteristic of the substrate film recited in Claim 17, because

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bioabsorbability in the claimed adhesive sheet would make the adhesive sheet useless ...” (Brief, pages 15-16, bridging paragraph), the Examiner notes that Appellants fail to provide any evidence regarding how bioabsorbability would make the adhesive sheet useless, and are reminded that in the absence of factual support, attorney’s argument cannot be taken as evidence.

Finally, with respect to Appellants’ argument “... Webster ‘426 has no relationship to the polymer blend disclosed in Bezwada ‘687 ... Bezwada ‘687 teaches that polyoxaesters thereof are hydrolytically unstable, such that it breaks down into small segments when exposed to moisture bodily tissue ... a person of ordinary skill in the art would not have been motivated to combine the teachings ...” (Brief, pages 17-18, bridging paragraph), the Examiner notes: 1) since both Bezwada and Webster are directed to the field of endeavor (wound dressing), their teachings are clearly combinable; 2) while Bezwada teaches that polyoxaester readily breaks down into small segments when exposed to moist bodily tissue, so as to provide the beneficial bioabsorbable property of a wound dressing (column 5, lines 57-62), nowhere does Bezwada teach such a breakdown of a polymer into smaller molecular segments as being detrimental to the use as a wound dressing sheet, and it is not seen how this bioabsorbable property would prevent it from being modified by Webster to improve its adherence to the intact skin. Appellants’ argument appears to be misplaced and is not persuasive.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the **TWO MONTH** time period set forth above. See 37 CFR 1.136(b) for extensions of time to

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reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,


Victor Chang
Examiner
Art Unit 1771

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

Jacqueline Stone

Conferees:

Terrel H. Morris



Carol D. Chaney

